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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,919	03/08/2002	Kjell Olmarker	003300-914	1488

7590

06/08/2004

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EXAMINER
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MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/092,919	<b>Applicant(s)</b> OLMARKER, KJELL	
	<b>Examiner</b> Prema M Mertz	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 March 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-12, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering infliximab, a monoclonal antibody to TNF, classified in class 424, subclass 145.1.
  - II. Claims 1-12, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering CDP-571, a monoclonal antibody to TNF, classified in class 424, subclass 145.1.
  - III. Claims 1-12, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering D2E7, a monoclonal antibody to TNF, classified in class 424, subclass 145.1.
  - IV. Claims 1-12, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering CDP-870, a monoclonal antibody to TNF, classified in class 424, subclass 145.1.
  - V. Claims 1-10, 13-14, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering etanercept, a soluble TNF receptor, classified in class 514, subclass 2.
  - VI. Claims 1-10, 15, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering a receptor antagonist, class and subclass undeterminable.

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- VII. Claims 1-10, 16, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering an antisense nucleotide, classified in class 514, subclass 44.
- VIII. Claims 1-10, 17, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering tetracyclines, classified in class 514, subclass 680.
- IX. Claims 1-10, 17, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering chemically modified tetracyclines, classified in class 514 , subclass 680+.
- X. Claims 1-10, 17, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Prinomastat, class and subclass undeterminable.
- XI. Claims 1-10, 17, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Batimastat, class and subclass undeterminable.
- XII. Claims 1-10, 17, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Marimastat, class and subclass undeterminable.
- XIII. Claims 1-10, 17, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering KB-R7785, class and subclass undeterminable.

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- XIV. Claims 1-10, 17, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering TIMP-1, classified in class 514, subclass 2
- XV. Claims 1-10, 17, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering chemically TIMP-2, classified in class 514, subclass 2.
- XVI. Claims 1-10, 17, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering chemically adTIMP-1, classified in class 514, subclass 44.
- XVII. Claims 1-10, 17, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering chemically adTIMP-2, classified in class 514, subclass 44.
- XVIII. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Norfloxacin, classified in class 514, subclass 279+.
- XIX. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Levofloxacin, classified in class 514, subclass 279+.
- XX. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Enoxacin, classified in class 514, subclass 279+.

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- XXI. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Sparfloxacin, classified in class 514, subclass 279+.
- XXII. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Temafloxacin, classified in class 514, subclass 279+.
- XXIII. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Moxifloxacin, classified in class 514, subclass 279+.
- XXIV. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Gatifloxacin, classified in class 514, subclass 279+.
- XXV. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Gemifloxacin, classified in class 514, subclass 279+.
- XXVI. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Grepafloxacin, classified in class 514, subclass 279+.
- XXVII. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Trovafloxacin, classified in class 514, subclass 279+.

XXVIII. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Ofloxacin, classified in class 514, subclass 279+.

XXIX. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Ciprofloxacin, classified in class 514, subclass 279+.

XXX. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Pefloxacin, classified in class 514, subclass 279+.

XXXI. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Lomefloxacin, classified in class 514, subclass 279+.

XXXII. Claims 1-10, 18, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Temafloxacin, classified in class 514, subclass 279+.

XXXIII. Claims 1-10, 19, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering CC-1088, classified in class 514, subclass 294.

XXXIV. Claims 1-10, 19, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering CDC-501 classified in class 514, subclass 294.

XXXV. Claims 1-10, 19, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering CDC-801, classified in class 514, subclass 294.

XXXVI. Claims 1-10, 19, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering Linomide, classified in class 514, subclass 294.

XXXVII. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering prostaglandins, classified in class 514, subclass 573.

XXXVIII. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering phosphodiesterase I inhibitors, class and subclass undeterminable.

XXXIX. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering phosphodiesterase II inhibitors, class and subclass undeterminable.

XXXX. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering phosphodiesterase III inhibitors, class and subclass undeterminable.

XXXXI. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering phosphodiesterase IV inhibitors, class and subclass undeterminable.



XXXXXII. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering phosphodiesterase V inhibitors, class and subclass undeterminable.

XXXXXIII. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering cyclosporin, classified in class 514, subclass 11.

XXXXXIV. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering pentoxifyllin, classified in class 514, subclass 258.

XXXXXV. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering hydroxamic acid derivatives, classified in class 514, subclass 553.

XXXXXVI. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering melanin agonists, class and subclass undeterminable.

XXXXXVII. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering melanocortin agonists, class and subclass undeterminable.

XXXXXVIII. Claims 1-10, 20, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering lazaroids, class and subclass undeterminable.

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XXXXIX. Claims 1-10, 21-22, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering IL-1 $\alpha$  and/or IL-1 $\beta$  blocking substance, class and subclass undeterminable.

XXXXX. Claims 1-10, 23, 24-25, drawn to a method for prevention or reduction of scar tissue and/or adhesion formation by administering lactoferrin, classified in class 514, subclass 23.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XXXXX are independent and distinct, each from the other, because the methods are practiced with materially different products which are structurally and chemically different, the novelty of the inventions lying in the products being administered and not the processes. The only feature in common in the instant inventions is "a method for prevention or reduction of scar tissue and/or adhesion formation", which does not constitute the special technical feature lacking from the prior art because this method can be used with a composition other than the instant products such as EGF. Distinctness is further shown because each of these products in each method can be made and used without any one or more of the other products. The products in the different Groups are physically, chemically and biologically distinct from each other, and if patentable would support separate patents. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of a monoclonal antibody to TNF with the claimed method would not necessarily reveal art for an association of quinolones or thalidomide derivatives with the claimed method.

2. This application contains claims directed to the following patentably distinct species of conditions in the claimed invention:

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In claims 4-10:

Post-traumatic tissue injury, surgery, thermic injury, bleeding, infarction, toxic influence, cystic fibrosis.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from one of the claims for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as

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defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Prema Mertz*  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
March 22, 2004